

PATENT COOPERATION TREATY

PCT



INTERNATIONAL PRELIMINARY REPORT ON PATENTABILITY

(Chapter II of the Patent Cooperation Treaty)

(PCT Article 36 and Rule 70)

REC'D 25 JUL 2006

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Applicant's or agent's file reference WAMP100908WO		FOR FURTHER ACTION	See Form PCT/IPEA/416
International application No. PCT/GB2005/001102	International filing date (day/month/year) 23.03.2005	Priority date (day/month/year) 25.03.2004	
International Patent Classification (IPC) or national classification and IPC INV. A61F2/06 F15D1/06 B29C45/14			
Applicant TAYSIDE FLOW TECHNOLOGIES LTD et al.			
<p>1. This report is the international preliminary examination report, established by this International Preliminary Examining Authority under Article 35 and transmitted to the applicant according to Article 36.</p> <p>2. This REPORT consists of a total of 6 sheets, including this cover sheet.</p> <p>3. This report is also accompanied by ANNEXES, comprising:</p> <p>a. <input checked="" type="checkbox"/> sent to the applicant and to the International Bureau) a total of 5 sheets, as follows:</p> <p><input checked="" type="checkbox"/> sheets of the description, claims and/or drawings which have been amended and are the basis of this report and/or sheets containing rectifications authorized by this Authority (see Rule 70.16 and Section 607 of the Administrative Instructions).</p> <p><input type="checkbox"/> sheets which supersede earlier sheets, but which this Authority considers contain an amendment that goes beyond the disclosure in the international application as filed, as indicated in item 4 of Box No. I and the Supplemental Box.</p> <p>b. <input type="checkbox"/> (sent to the International Bureau only) a total of (indicate type and number of electronic carrier(s)) , containing a sequence listing and/or tables related thereto, in electronic form only, as indicated in the Supplemental Box Relating to Sequence Listing (see Section 802 of the Administrative Instructions).</p>			
<p>4. This report contains indications relating to the following items:</p> <p><input checked="" type="checkbox"/> Box No. I Basis of the report</p> <p><input type="checkbox"/> Box No. II Priority</p> <p><input type="checkbox"/> Box No. III Non-establishment of opinion with regard to novelty, inventive step and industrial applicability</p> <p><input type="checkbox"/> Box No. IV Lack of unity of invention</p> <p><input checked="" type="checkbox"/> Box No. V Reasoned statement under Article 35(2) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement</p> <p><input type="checkbox"/> Box No. VI Certain documents cited</p> <p><input checked="" type="checkbox"/> Box No. VII Certain defects in the international application</p> <p><input type="checkbox"/> Box No. VIII Certain observations on the international application</p>			
Date of submission of the demand 25.01.2006		Date of completion of this report 24.07.2006	
Name and mailing address of the international preliminary examining authority:  European Patent Office D-80298 Munich Tel. +49 89 2399 - 0 Tx: 523656 epmu d Fax: +49 89 2399 - 4465		Authorized officer Steiner, B Telephone No. +49 89 2399-6035 	

**INTERNATIONAL PRELIMINARY REPORT
ON PATENTABILITY**

International application No.
PCT/GB2005/001102

Box No. I Basis of the report

1. With regard to the **language**, this report is based on

- ☒ the international application in the language in which it was filed
- ☐ a translation of the international application into , which is the language of a translation furnished for the purposes of:
 - ☐ international search (under Rules 12.3(a) and 23.1(b))
 - ☐ publication of the international application (under Rule 12.4(a))
 - ☐ international preliminary examination (under Rules 55.2(a) and/or 55.3(a))

2. With regard to the **elements*** of the international application, this report is based on *(replacement sheets which have been furnished to the receiving Office in response to an invitation under Article 14 are referred to in this report as "originally filed" and are not annexed to this report):*

Description, Pages

1-18 as originally filed

Claims, Numbers

1-37 received on 25.01.2006 with letter of 24.01.2006

Drawings, Sheets

1/2, 2/2 as originally filed

- ☐ a sequence listing and/or any related table(s) - see Supplemental Box Relating to Sequence Listing

3. ☐ The amendments have resulted in the cancellation of:

- ☐ the description, pages
- ☐ the claims, Nos.
- ☐ the drawings, sheets/figs
- ☐ the sequence listing (*specify*):
- ☐ any table(s) related to sequence listing (*specify*):

4. ☐ This report has been established as if (some of) the amendments annexed to this report and listed below had not been made, since they have been considered to go beyond the disclosure as filed, as indicated in the Supplemental Box (Rule 70.2(c)).

- ☐ the description, pages
- ☐ the claims, Nos.
- ☐ the drawings, sheets/figs
- ☐ the sequence listing (*specify*):
- ☐ any table(s) related to sequence listing (*specify*):

* *If item 4 applies, some or all of these sheets may be marked "superseded."*

INTERNATIONAL PRELIMINARY REPORT ON PATENTABILITY

International application No.
PCT/GB2005/001102

Box No. V Reasoned statement under Article 35(2) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement

1. Statement

Novelty (N)	Yes: Claims	4 - 7, 9 - 37
	No: Claims	1, 2, 3, 8
Inventive step (IS)	Yes: Claims	5, 9, 12 - 37
	No: Claims	1, 2, 4, 6 - 8, 10, 11
Industrial applicability (IA)	Yes: Claims	1 - 37
	No: Claims	

2. Citations and explanations (Rule 70.7):

see separate sheet

Box No. VII Certain defects in the international application

The following defects in the form or contents of the international application have been noted:

see separate sheet

Re Item V

**Reasoned statement with regard to novelty, inventive step or industrial applicability;
citations and explanations supporting such statement**

1. Reference is made to the following documents:

- D1: US-B1-6 361 558 (HIESHIMA GRANT ET AL) 26 March 2002 (2002-03-26)
- D2: WO 03/053495 A (TRIVASCULAR, INC; CHOBOTOV, MICHAEL, V; STEPHENS, W., PATRICK) 3 July 2003 (2003-07-03)
- D3: US-A-5 609 624 (KALIS ET AL) 11 March 1997 (1997-03-11)
- D4: DE 25 20 998 A1 (BROWN,BOVERI & CIE AG) 25 November 1976 (1976-11-25)
- D5: WO 01/28746 A (SVENSKA ROTOR MASKINER AB; SUNDSTROEM, MATS; TIMUSKA, KARLIS) 26 April 2001 (2001-04-26)
- D6: BAUGH J A ET AL: "FLEXIBLE AUGER" IBM TECHNICAL DISCLOSURE BULLETIN, IBM CORP. NEW YORK, US, vol. 19, no. 10, March 1977 (1977-03), page 3665, XP001173675 ISSN: 0018-8689
- D7: US 2002/179166 A1 (HOUSTON JOHN GRAEME ET AL) 5 December 2002 (2002-12-05)
- D8: EP-A-1 312 321 (TAYSIDE FLOW TECHNOLOGIES LIMITED) 21 May 2003 (2003-05-21)

2.1 The present application does not meet the criteria of Article 33(1) PCT, because the subject-matter of claim 1 is not new in the sense of Article 33(2) PCT.

The document D7 discloses (the references in parentheses applying to this document): A tubular conduit comprising: a tubular portion made from a flexible material (paragraph 48); an axially extending external helical formation located around then outside of the tubular portion for supporting the tubular portion (paragraph 4; paragraph 54; figure 7A, feature 14a, 14b); and an axially extending internal helical protrusion located around the inside of the tubular portion (paragraph 5; paragraph 6; paragraph 54; figure 7A, features 13a, 13b, 13c) for imparting a helical flow to a fluid passing through the tubular portion (paragraph 5).

2.2 Document D8 discloses all of the features of claim 1 except for the external helical formation. Since external helical formations, for the purpose of strengthening conduits

are well known, e.g. from documents D1 or D3, claim 1 is also considered not to be inventive over the combination of documents D1 and D8.

3. Dependent claims 2 - 4, 6 - 8, 10 and 11 do not contain any features which, in combination with the features of any claim to which they refer, meet the requirements of the PCT in respect of novelty and/or inventive step, see document D1, D7 and D8 and the corresponding passages cited in the search report.
4. The combination of the features of dependent claims 5, 9, 12 and 13 is neither known from, nor rendered obvious by, the available prior art. The features of these claims are not disclosed in any single prior art document and there is no indication that it would be obvious to combine prior art documents to arrive at the features of these claims.
- 5.1 Documents D4 - D6 each disclose methods of moulding axially extending, helical forms around the exterior of solid cylindrical forms.

The subject-matter of claim 14 differs in that the first step of claim 14 is that of providing a tubular portion made of a flexible material. The moulding liquid then flows and is solidified around the exterior of this tube.

The subject-matter of claim 14 is therefore new (Article 33(2) PCT).

- 5.2 The problem to be solved by the present invention may be regarded as that of manufacturing a tubular conduit with an external helical form.

The solution to this problem proposed in claim 14 of the present application is considered as involving an inventive step (Article 33(3) PCT) because none of the manufacturing methods of D4, D5 or D6 would be suitable for use with a flexible tubular conduit.

- 5.2 Claims 15 - 30 are dependent on claim 14 and as such also meet the requirements of the PCT with respect to novelty and inventive step.
6. Document D2 discloses the following features of claim 31:

a mould for providing a helical formation onto an tubular conduit, a mandrel and a moulding block.

The subject-matter of claim 31 differs in that claim 31 also has the feature of the mandrel having an axially extending helical channel on its outer surface.

The subject-matter of claim 31 is therefore new (Article 33(2) PCT).

- 6.2 The problem to be solved by the present invention may be regarded as that of providing an apparatus for the manufacture of a tubular conduit with both an internal and an external helical form.

The solution to this problem proposed in claim 31 of the present application is considered as involving an inventive step (Article 33(3) PCT) because the feature of a helical conduit on a mandrel is not disclosed in the prior art.

- 6.3 Claims 32 - 37 are dependent on claim 14 and as such also meet the requirements of the PCT with respect to novelty and inventive step.

Re Item VII

Certain defects in the international application

- 7.1 Independent claims 1, 14 and 31 are not in the two-part form in accordance with Rule 6.3(b) PCT, which in the present case would be appropriate, with those features known in combination from the prior art being placed in the preamble (Rule 6.3(b)(I) PCT) and with the remaining features being included in the characterising part (Rule 6.3(b)(ii) PCT).
- 7.2 The features of the claims are not provided with reference signs placed in parentheses (Rule 6.2(b) PCT).

CLAIMS

1. A tubular conduit comprising: a tubular portion made from a flexible material; an axially extending external helical formation located around the outside of the tubular portion for supporting the tubular portion; and an axially
5 extending internal helical protrusion located around the inside of the tubular portion for imparting a helical flow to a fluid passing through the tubular portion.
2. A tubular conduit according to claim 1 for use as a graft, preferably a vascular graft.
- 10 3. A tubular conduit according to claim 1 or 2 wherein the internal helical protrusion comprises a section of the tubular portion deformed by an axially extending deformation helix.
4. A tubular conduit according to claim 3 wherein the axially extending deformation helix is made from polyurethane.
- 15 5. A tubular conduit according to claim 3 or 4 wherein the axially extending deformation helix is sintered to the flexible material of the tubular portion.
6. A tubular conduit according to any one of the preceding claims wherein the external helical formation has a different helix angle from the
20 internal helical protrusion.
7. A tubular conduit according to claim 6 wherein the helix angle of the external helical formation is greater than the helix angle of the internal helical protrusion.
8. A tubular conduit according to any one of the preceding claims wherein
25 the helix angle of the internal helical protrusion is between 8° and 20°.

9. A tubular conduit according to any one of the preceding claims wherein the helix angle of the external helical formation is greater than 50° and preferably between 65° and 80°.
10. A tubular conduit according to any one of the preceding claims wherein
5 the tubular portion is made from ePTFE.
11. A tubular conduit according to any one of the preceding claims wherein the external helical formation is made from polyurethane.
12. A tubular conduit according to any one of the preceding claims wherein the inside of the tubular portion has a carbon coating.
- 10 13. A tubular conduit according to any one of the preceding claims wherein the external helical formation is sintered to the flexible material of the tubular portion.
14. A method of making a tubular conduit comprising the steps of:
- (a) providing a tubular portion made from a flexible material;
- 15 (b) flowing a moulding liquid in an axially extending, helical form around the exterior of the tubular portion; and
- (c) solidifying the moulding liquid.
15. A method according to claim 14 wherein step (b) comprises the step of
20 flowing a moulding liquid in two axially extending helical forms around the exterior of the tubular portion.
16. A method according to claim 15 wherein the two helical forms each has a different helix angle.
17. A method according to any one of claims 14 to 16 wherein step (b) comprises: (i) deforming the tubular portion so as to provide an internal helical

protrusion on the inside of the tubular portion and a corresponding external helical groove; and (ii) flowing the moulding liquid into the external helical groove to form an axially extending helical form.

18. A method according to claim 17 as dependent on claim 16 wherein the
5 helix angle of the moulding liquid flowed into the external helical groove is less than the helix angle of the other axially extending helical form.

19. A method according to claim 17 or 18 wherein the helix angle of the moulding liquid flowed into the external helical groove is between 8° and 20°.

20. A method according to any one of claims 14 to 19 wherein step (b)
10 comprises locating the tubular portion over a mandrel; and encasing the tubular portion within a mould such that the tubular portion is sandwiched between the mandrel and the mould.

21. A method according to claim 20 as dependent from claim 17, 18 or 19
15 wherein the mandrel has an axially extending helical channel on its surface and wherein step (i) further comprises the step of introducing the moulding liquid between the tubular portion and the mould such that the moulding liquid deforms the tubular portion by pressing the tubular portion into the helical channel on the mandrel to provide the internal helical protrusion.

22. A method according to claim 21 further comprising, between the steps
20 of locating of the tubular portion over the mandrel and encasing the tubular portion within the mould, the step of: pushing the tubular portion at least partially into the helical channel on the mandrel.

23. A method according to claim 21 or 22 wherein the step of introducing
25 the moulding liquid comprises injecting the moulding liquid into the mould above the helical channel in the mandrel.

24. A method according to any one of claims 20 to 23 wherein the mould has an axially extending helical channel about its inside surface and wherein step (b) further comprises the step of introducing the moulding liquid between the tubular portion and the mould such that the moulding liquid flows into the helical channel in the mould.

25. A method according to claim 24 wherein the helix angle of the helical channel in the mould is greater than 50°, and preferably is between 65° and 80°.

26. A method according to any one of claims 14 to 25 further comprising, between steps (b) and (c), the step of sintering the moulding liquid onto the flexible material of the tubular portion.

27. A method according to any one of claims 14 to 26 wherein step (b) is carried out between 600 and 800 kPa and between 170 and 210°C, preferably at 689 kPa and 190°C.

28. A method according to any one of claims 14 to 27 further comprising the step of coating the inner surface of the tubular portion with carbon.

29. A method according to any one of claims 14 to 28 wherein the moulding liquid is polyurethane.

30. A method according to any one of claims 14 to 29 wherein the flexible material is ePTFE.

31. A mould for providing a helical formation onto a tubular conduit comprising:

a mandrel on which the tubular conduit is locatable, the mandrel having an axially extending helical channel on its outer surface; and

a moulding block having a bore for receiving the mandrel with the tubular conduit located thereon.

32. A mould according to claim 31 wherein the bore has an axially extending helical channel on its inner surface.

5 33. A mould according to claim 32 wherein the helix angle of the helical channel on the bore is different from the helix angle of the helical channel on the mandrel.

34. A mould according to claim 33 wherein the helix angle of the helical channel on the bore is greater than the helix angle of the helical channel on
10 the mandrel.

35. A mould according to any one of claims 31 to 34 wherein the helix angle of the helical channel on the mandrel is between 8° and 20° .

36. A mould according to any one of claims 32 to 34 or claim 35 as dependent on claim 32 wherein the helix angle of the helical channel on the
15 bore is greater than 50° and preferably between 65° and 80° .

37. A method according to any one of claims 14 to 30 or a mould according to any one of claims 31 to 36, wherein the tubular conduit is a vascular graft.